2014-1729

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SMITH & NEPHEW, INC. and JOHN O. HAYHURST, M.D.,

Plaintiffs-Appellees,

v.

ARTHREX, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Oregon in case no. 04-CV-0029, Judge Michael W. Mosman.

NON-CONFIDENTIAL BRIEF FOR DEFENDANT-APPELLANT ARTHREX, INC.

Dated: September 15, 2014

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No. 2014-1729

CERTIFICATE OF INTEREST

Counsel for Defendant-Appellant, Arthrex, Inc. certifies the following:

1. The full name of every party represented by me is:

Arthrex, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court are:

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CONFIDENTIAL MATERIAL OMITTED

Confidential material subject to protective order has been deleted from the nonconfidential version of this brief. The deleted portions on pages 6, 12, 29 and 41 describe information designated confidential by Smith & Nephew, including market and competitor information. The deleted portions on pages 39-41 contain Arthrex's confidential sales information.

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STATEMENT OF RELATED CASES

There were three prior appeals to this Court from the same civil action. The first appeal was dated December 2, 2009 and titled *Smith & Nephew, Inc. and John O. Hayhurst, M.D. v. Arthrex, Inc.* (Appeal No. 2009-1091, -1192), 355 Fed. Appx. 384, 2009 WL 4282012 (C.A.Fed. (Or.)) (unpublished) (Judges Bryson, Clevenger, Dyk).

The second appeal was decided on January 16, 2013 and titled *Smith &Nephew, Inc. and John O. Hayhurst, M.D. v. Arthrex, Inc.* (Appeal No. 2012-1265), 502 Fed. Appx. 945, 2013WL 163823 (C.A.Fed. (Or.)) (unpublished) (Judges Lourie, Clevenger, Wallach).

The third appeal is pending and is titled *Smith &Nephew, Inc. and John O. Hayhurst, M.D. v. Arthrex, Inc.* (Appeal No. 2014-1691, -1694). This Court recently ordered that oral arguments in that third appeal and the present appeal be treated as companion cases. Dkt. No. 13.

A second civil action, filed June 12, 2008, is currently pending in the same district court in which S&N is alleging infringement by different suture anchors not included in this civil action. That second civil action is titled *Smith & Nephew, Inc. and John O. Hayhurst, MD. v. Arthrex, Inc.*, CV08714-MO. The district court has indicated it plans to have that second civil action re-assigned to another judge.

STATEMENT OF JURISDICTION

This action arises under the Patent Laws of the United States, Title 35, United States Code. The district court had subject matter jurisdiction over this patent infringement action under 28 U.S.C. §§ 1331 and 1338(a). A Notice of Appeal, pursuant to Rule 4(a)(1) of the Federal Rules of Appellate Procedure, was filed by Arthrex on August 18, 2014. A36664-66. This Court has jurisdiction under 28 U.S.C. § 1295.

STATEMENT OF ISSUES ON APPEAL

The issues on appeal are:

i) Did the district court err in denying Arthrex's Rule 60(b)(6) motion to reopen the judgment of infringement as to its SutureTak anchors where the Supreme Court decision in *Limelight Networks, Inc. v. Akamai Techs, Inc.*, 134 S. Ct. 2111 (2014), resurrected Arthrex's divided infringement defense that all steps of the method claims are not attributable to one single actor, and all factors for granting Rule 60(b)(6) relief favor reopening the judgment;

ii) Did the district court err in finding that this Court's prior mandate in this case prohibited the district court from considering Arthrex's divided infringement argument and that Arthrex was prevented from raising divided infringement as a defense at the second trial because it had not been raised at the first trial (which resulted in a hung jury), even though the latest pronouncement on divided infringement at that time left Arthrex without such a defense.

STATEMENT OF THE CASE SETTING OUT THE FACTS RELEVANT TO THE ISSUES

I. INTRODUCTION

In June 2014, the Supreme Court decided *Limelight Networks, Inc. v. Akamai Techs, Inc.*, 134 S. Ct. 2111 (2014), holding that to prove induced infringement, the patentee must show that there was a single direct infringer. *Id.* at 2118. In doing so, the Supreme Court reversed the Federal Circuit's *en banc* decision in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (*en banc*), where this Court had held that an induced infringement claim was appropriate in the absence of a single direct infringer. Thus, under that now overruled law, two entities could combine to practice all the steps of a method claim, even without direction and control or an agency relationship. *Id.* at 1309.

The new Supreme Court decision, the impetus for the Rule 60(b)(6) motion filed by defendant Arthrex, Inc. ("Arthrex") below, has significant ramifications for this case because it may decisively impact Arthrex's "divided infringement defense." Plaintiffs Smith & Nephew, Inc. and Dr. John Hayhurst (collectively, "S&N") sued Arthrex for indirectly infringing U.S. Patent No. 5,601,557 ("the '557 patent"), involving method claims for using a suture anchor in surgery. Arthrex has a divided infringement defense because, as it relates to the principal products accused in this case (Arthrex's SutureTak anchors), Arthrex performs one

of the method steps ("attaching a suture to a member") while S&N asserts that the surgeons perform the remaining steps. There is no allegation that the surgeons, the accused direct infringers, direct or control Arthrex.

As described in detail below, the history of Arthrex's efforts to raise this defense, as well as the legal landscape of the divided infringement defense, has been long and tortious. What is most important for this appeal, however, is that ever since this Court decided *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007), which clarified the prior law so that, to prove direct infringement, one actor must perform all the steps either itself or by another under the direct infringer's direction and control, Arthrex has been trying to raise the divided infringement defense. The district court, however, prohibited Arthrex from raising the defense because it believed that Arthrex had waived it (although it never disputed Arthrex's showing that divided infringement, if raised, is a complete defense to S&N's allegations against Arthrex's SutureTak anchors).

Arthrex raised the district court's refusal to allow this defense in the two prior appeals in this case.[1] But this Court, in deciding those appeals, issued no written opinion deciding whether the district court's action was correct. In a 2009

[1] *Smith & Nephew, Inc. and John O. Hayhurst, M.D. v. Arthrex, Inc.* (Appeal No. 2009-1091, -1192), 355 Fed. Appx. 384, 2009 WL 4282012 (Fed. Cir. 2009) ("*S&N I*"), and *Smith &Nephew, Inc. and John O. Hayhurst, M.D. v. Arthrex, Inc.* (Appeal No. 2012-1265), 502 Fed. Appx. 945, 2013WL 163823 (Fed. Cir. 2013) ("*S&N II*").

appeal (*S&N I*), it did not do so because it ruled in Arthrex's favor on other issues; as a result, the Court specifically stated that "it [was] not necessary to address Arthrex's additional arguments challenging that judgment." *S&N I*, 355 Fed. Appx. at 389. In a 2013 appeal (*S&N II*), it did not need to comment on the district court's actions because, while that appeal was pending, this Court decided *Akamai*.[2] Since it is undisputed that Arthrex would have no divided infringement defense under *Akamai*, there was no need for this Court to decide whether the district court's prohibition for other reasons was correct.[3]

The resolution of this issue is no small matter. The jury awarded S&N with approximately $85 million in damages (higher today in light of post-trial damages and interest), almost all of which would disappear if Arthrex is entitled to raise its divided infringement defense.[4] Before it is required to pay such substantial damages, it is entitled to an appellate ruling whether the district court properly

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[2] Briefing was concluded in *S&N II* with S&N's reply brief on August 13, 2012 (*see* A33432), and *Akamai* was decided on August 31, 2012 (*see* 692 F.3d at 1301). Oral argument in *S&N II* occurred on November 8, 2012. *S&N II*, Appeal No. 2012-1265, Dkt. No. 36

[3] The only express comment by the Court on the divided infringement issue was when a motions panel agreed with Arthrex and granted Arthrex's emergency motion to stay the injunction in *S&N I*. *Infra* at 10.

[4] Arthrex's divided infringement defense does not apply to the other family of products (PushLock) involved in the case. [redacted] and a portion of the remaining $17 million awarded as reasonable royalties are attributable to Arthrex's sale of SutureTak products, where Arthrex does have its divided infringement defense.

prohibited Arthrex from raising its divided infringement defense. Should the Court agree with Arthrex that it was entitled to raise this valid defense, as Arthrex believes it will, it will avoid a significant injustice and prevent the payment of tens of millions of dollars that should not be made. Rule 60(b) is the appropriate vehicle to prevent that injustice.

II. HISTORY OF THE CASE

A. District Court Proceedings

S&N accuses Arthrex of indirectly infringing the '557 patent, a method patent for using a surgical device.[5] The surgeons who practice the surgical method are the accused direct infringers and Arthrex, a medical device company, is accused of inducing and contributing to the infringement through its sales of the "suture anchors" used to perform the surgical method and its efforts instructing that use.

For example, claim 1 requires the following steps:

> A method for anchoring in bone a member and attached suture, *the method comprising the steps of:*
>
> forming a hole in the bone;
>
> *attaching a suture to a member;*

[5] This case has a complex history involving three trials and three appeals. The instant appeal has been combined as a companion case with another pending appeal in this case, No. 2014-1691, -1694. That appeal is fully briefed and this Court has ordered that the oral argument of the two appeals to be combined. Dkt. No. 13. The factual background is recounted here only as relevant to the divided infringement issue involved in this appeal.

> lodging the member within the hole by pressing the member with attached suture into the hole; and
>
> attaching tissue to the suture so that the tissue is secured against the bone.

A155 (emphasis added). For one of the two family of suture anchors accused in this action, Arthrex's SutureTak anchors, the suture anchors are sold with the suture pre-attached to the anchor by *Arthrex*. Thus, for these products, Arthrex performs the "attaching the suture to the member" step, while S&N asserts that the surgeons (the accused direct infringers) perform the other method steps.[6] As a result, there is no single direct infringer (and there is no allegation that the surgeons direct and control Arthrex), and Arthrex cannot be liable for indirect infringement.

The first trial in this case, which resulted in a hung jury, occurred in June 2007. A38-43. At that time, this Court's most recent pronouncement on divided infringement was from *On Demand Machine Corp. v. Ingram Indus.*, 442 F.3d 1331, 1344-45 (Fed. Cir. 2006), where the Federal Circuit approved a jury instruction of infringement based on the combined action of multiple parties. The approved instruction stated that a finding of infringement "results from the participation and combined action(s) of more than one person or entity." *Id*.

[6] For the other accused family of products, "PushLock" anchors, the suture comes unattached and is attached by the surgeon. Accordingly, the divided infringement defense does not apply to the PushLock products.

S&N's direct infringement evidence at the first trial pointed to actions of the surgeons performing all method steps of the '557 patent *except* for the "attaching a suture to a member" step. For that step, S&N pointed to actions by *Arthrex*. Its expert testified at the 2007 trial:

> Q. The next one is, "attaching a suture to the member." Let's talk about member in a minute. Let's talk about attaching a suture to, let's just say that the member is the actual anchor. Does *Arthrex* do that?
>
> A. *Yes. They sell them with pre-attached sutures for the use of the surgeon.*

A8350.058 (emphasis added). S&N's approach was entirely consistent with the jury instruction approved by this Court in *On Demand*.

After the first trial ended, the Federal Circuit decided *BMC*, 498 F.3d at 1381-82, which held that, to prove direct infringement, one actor must perform all the steps either itself or by another under the direct infringer's direction and control. As this Court explained, *BMC* clarified the confusion on divided infringement law resulting from the Court's *On Demand* decision. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008).

Prior to the second trial, Arthrex brought *BMC* to the district court's attention in opposition to one of S&N's *in limine* motions (no. 37), contending that it now had a viable "divided infringement" defense with respect to the SutureTak products. *E.g.*, A10309-11. The district court, however, would not allow Arthrex to raise the defense. The district court issued no written opinion on this issue,

merely granting S&N's *in limine* motion. A10815. Its statements at the pretrial hearing where the *in limine* motions were discussed were no more illuminating. The district court took no argument on the issue, stating only that it would require S&N to provide "no proof of attaching a suture to the member," characterizing Arthrex's argument as a defense that is "too late in the game to raise." A10806; A10815.

B. The First Appeal to this Court (*S&N I)*

The second trial (in 2008) resulted in a judgment for S&N and the district court enjoined the sale of the accused SutureTak anchors. A11924-26; A11927-28; A11931-943. Arthrex appealed, accompanied by an emergency motion to stay the injunction which a motions panel of the Court granted. *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 09-1091, Order, Dkt. No. 22 (Fed. Cir. Jan. 14, 2009) (A30760-63).

The divided infringement argument was the only issue discussed in the Order granting the emergency motion. A30760-63. The Court noted the district court's view that Arthrex had "waived the issue by not raising it in the first trial." A30762. Notwithstanding this, the panel "conclude[d] that there is a strong likelihood of success on the merits of Arthrex's appeal regarding the Bio-Suture Tak anchor." A30763.

The appellate process continued and Arthrex prevailed in the appeal. The principal issue in the merits briefing was the district court's construction of "resilience," an issue that went to both the SutureTak and PushLock anchors. This Court "reversed the judgment of infringement against Arthrex" because the district court's construction that resilience need only contribute in part to lodging was erroneous and this Court remanded for a new trial. *S&N I*, 355 Fed. Appx. at 389. While Arthrex also challenged the judgment (for SutureTak) based on its divided infringement defense, this Court did not expressly address that issue. It did, however, state:

> Because we have reversed the judgment of infringement against Arthrex, *it is not necessary to address Arthrex's additional arguments challenging that judgment.*

Id. (emphasis added).

C. District Court Proceedings on Remand from *S&N I*

On remand, divided infringement was one of the grounds upon which Arthrex moved for summary judgment. A11991-92. Notwithstanding this Court's statement that it did not consider Arthrex's additional arguments challenging the judgment (which had to include the divided infringement defense), the district court construed the Federal Circuit's mandate narrowly and held that the mandate precluded it from further consideration of the divided infringement issue. A13363-64. The district court went on to explain that if it could decide the issue, it would

uphold its earlier ruling that Arthrex had waived the issue by not raising it at the first trial. A13364. The district court based this ruling on its mistaken view that "S&N never argued the combined actions of Arthrex and the surgeons created joint liability for infringement, or even that the actions combined at all." A13364-65.

In light of the district court's ruling, the divided infringement issue played no role at the third trial. At that trial, the jury found for S&N, and awarded damages of approximately $85 million. [redacted][7] The remaining amount (about $17 million) was for reasonable royalties covering sales of some SutureTak products as well as some PushLock products. A16500-501; A18710-11. After trial, the district court entered JMOLs in Arthrex's favor on both direct infringement and indirect infringement (as it indicated it would do at trial because, in its view, the evidence was so overwhelmingly in favor of Arthrex). A17948; A19439-441.

D. The Second Appeal to this Court (*S&N II)*

This time, S&N appealed, arguing that the district court should not have entered the JMOLs. A17951-52. In Arthrex's responsive brief, Arthrex raised the divided infringement issue as an alternative reason to uphold the judgment as it pertained to the SutureTak family. A33424-28.

[7] Whether lost profits is appropriate is one of the issues pending in Appeal No. 2014-1691, -1694.

When the parties filed their respective briefs in *S&N II*, *BMC* was still the state of the law on divided infringement. After briefing was concluded, but before oral argument, this Court issued its *en banc* decision in *Akamai*, 692 F.3d 1301.[8] The *en banc* holding was that induced infringement could be found even if there was no direct infringer (a single entity performing all the steps alone or by another under its direction and control). *Id*. at 1309-11. It was enough if the inducing defendant carries out some steps and encourages others to carry out the remaining steps, even if no one would be liable as a direct infringer in such circumstances. *Id.* at 1309.

As a result of this *en banc* ruling, Arthrex no longer had a viable "divided infringement" argument. Arthrex attached the suture to the anchor and, according to S&N's theory of liability, it encouraged the surgeons to perform the remaining steps. Thus, based on this *en banc* ruling reversing prior Federal Circuit law, this Court had all the basis it needed to resolve the divided infringement issue against Arthrex without the need to consider any of the unrelated contentions of the parties.

Accordingly, the divided infringement issue did not come up at oral argument and this Court made no direct mention of that issue in its decision

[8] Briefing was concluded with S&N's reply brief on August 13, 2012 (*see* A33432), and *Akamai* was decided on August 31, 2012 (*see* 692 F.3d at 1301). Oral argument in the appeal in this case occurred on November 8, 2012. *S&N II*, Appeal No. 2012-1265, Dkt. No. 36.

reversing the district court's JMOL. *S&N II*, 502 Fed. Appx. 945. The Court did note that it "considered the parties' remaining arguments and conclude that they are without merit." *Id.* at 950.

E. Subsequent District Court Proceedings

On remand from the Federal Circuit in *S&N II*, the district court considered a series of motions from both parties. The district court's denial of Arthrex's motions to revisit the liability issues in light of the claim construction issued by this Court in *S&N II* and Arthrex's positions relating to the appropriate award of damages at trial and thereafter form the basis of Arthrex's pending appeal in No. 2014-1691, -1694.

In June 2014, while that appeal was pending, the Supreme Court issued its ruling reversing the Court's *en banc* decision in *Akamai*. *Limelight Networks*, 134 S. Ct. 2111. The Supreme Court ruled that there must be a direct infringement (which under current law requires a single direct infringer) for there to be liability for indirect infringement. *Id.* at 2117-19. Since Arthrex's divided infringement argument is and always has been predicated on the notion that there is no single direct infringer, this recent Supreme Court decision brings Arthrex's argument back to life.

On July 2, 2014, Arthrex filed a motion under Fed. R. Civ. P. 62.1 seeking an indicative ruling that the district court would grant the concurrently-filed Rule

60(b)(6) motion to reopen the judgment in light of the change of law resulting from the Supreme Court's decision in *Limelight Networks.* A36233-240; A36241-262.[9] Without a written opinion, the district denied both of Arthrex's motions on August 15, 2014. A1. Arthrex filed an immediate appeal on August 18, 2014. A36664-66. On August 29, 2014, the Court granted Arthrex's motion to consider this appeal a companion case with 2014-1691, -1694 (with a single oral argument) together with an expedited briefing schedule. Dkt. No. 13.

[9] Because this action was already on appeal, the proper procedure was to file the Rule 62.1 indicative ruling motion. That rule allows a district court (1) to indicate that it would grant the underlying motion once jurisdiction was conferred (or indicate that a substantial question is involved), (2) to defer action or (3) to deny the underlying motion. Fed. R. Civ. P. 62.1.

SUMMARY OF ARGUMENT

The district court should have granted Arthrex's Rule 60(b)(6) motion, as all the factors set forth by the Ninth Circuit in *Phelps v. Alameida*, 569 F.3d 1120 (9th Cir. 2009), are met. The Supreme Court's decision in *Limelight Networks* was a significant change of law that resurrected Arthrex's divided infringement defense. When this Court issued its decision in *S&N II*, Arthrex had no divided infringement defense. Right before issuing its decision in that appeal, this Court decided *Akamai en banc* which held that it was not necessary for a single entity to practice all steps of a method claim to support liability for induced infringement under ¶ 271(b). Under *Akamai*, it is undisputed that Arthrex had no divided infringement.

Under the current state of law in *Limelight Networks*, however, Arthrex is entitled to judgment because no single entity practices each step of the '557 method claims. Arthrex "attaches a suture to the member" (because the anchors come with the suture pre-attached) and the surgeons perform the remaining steps (and there is no allegation of direction and control). This change of law strongly supports a grant of Arthrex's Rule 60(b)(6) motion.

All the other *Phelps* factors support granting Rule 60 relief. Arthrex filed its motion immediately upon the issuance of the Supreme Court decision. Indeed, Arthrex has pursued its divided infringement defense at every stage since this

Court's decision in *BMC,* 498 F.3d 1373, clarified divided infringement law so that Arthrex had a viable defense. There is not and cannot have been a change of position and there are no "past effects" that would be disturbed if judgment was reopened. Final judgment was entered only late last year and the case is currently on appeal. There is no delay, as the case is still ongoing and Arthrex has sought expedited consideration of this motion below as well as in this Court. There plainly is a close connection between the case at hand and the intervening change in the law, as *Limelight Networks* reversed the Federal Circuit law and Arthrex's divided infringement defense is predicated on the precise issue addressed in *Limelight Networks*. Finally, there is no concern with comity, as this Court is intimately familiar with the issues in this case, particularly as it relates to divided infringement which was raised in both *S&N I* and *S&N II.*

The district court's consistent refusal to allow Arthrex to raise its divided infringement defense is error. The district court's reasoning that this Court's mandate in *S&N I* precluded it from further consideration of the divided infringement is wrong. The mandate rule does not bar the district court from considering issues that the Court of Appeals did not decide. Here, Arthrex prevailed on the appeal in *S&N I* on other grounds (improper claim construction) and this Court explicitly said that it was not considering Arthrex's other challenges

to the judgment (which included the district court's refusal to allow Arthrex to raise this defense).

The district court's refusal to allow Arthrex to raise its divided infringement defense is also error. When this case was first tried in 2007, this Court's most recent pronouncement on divided infringement was in *On Demand*, 442 F.3d 1331, where the Court approved a jury instruction that infringement can be found "from the participation and combined action(s) of more than one person or entity" without any direction or control or agency relationship. That changed by the Court's decision in *BMC,* which eliminated the confusion from *On Demand* and clarified that law on divided infringement. Under the holding of *BMC*, that a single entity must practice all limitations of the claim either itself or by others under its direction and control, Arthrex then had a viable divided infringement defense because no one entity practiced every limitation of the method claims. In light of *BMC*, the district court erred in refusing to allow Arthrex to pursue this defense.

S&N's other reasons that Arthrex does not have a viable divided infringement defense should be rejected. The "attaching a suture to a member" limitation is not a structural limitation. The language of the claims could not be clearer that it is a method step. S&N's reference to plication, an obsolete device that, at best, involves a fraction of one percent of Arthrex's SutureTak product,

should be rejected because S&N has no evidence that any surgeon used that device to remove the pre-attached suture and attach a different one. In fact, the only record evidence on the subject showed that the pre-attached suture was not removed.

Although the divided infringement issue was before this Court in both *S&N I* and *S&N II*, this Court did not have occasion to decide if the district court's rulings preventing Arthrex from raising the defense was correct. The Court did not decide it in *S&N I* because it ruled in favor of Arthrex on other grounds and it did not need to decide the issue in *S&N II* because *Akamai* had just been decided *en banc* (which eliminated Arthrex's defense). Before Arthrex is required to pay almost $100 million dollars, almost all of which would be eliminated if it is correct on its divided infringement defense, fundamental fairness dictates that this Court should render a clear decision on whether Arthrex can raise this valid defense. That is the purpose of Rule 60(b).

ARGUMENT

I. STANDARD OF REVIEW

Because the denial of a Rule 60(b) motion involves procedural issues unrelated to patent law, the Federal Circuit reviews the denial under the law of the regional circuit. *CEATS, Inc. v. Cont'l Arilines, Inc.*, 755 F.3d 1356, 1360 (Fed. Cir. 2014). The Ninth Circuit reviews a district court's denial of a motion under Rule 60(b) for abuse of discretion. *Phelps v. Alamedia,* 569 F.3d 1120, 1131 (9th Cir. 2009). A district court abuses its discretion in denying a Rule 60(b) motion, among other things, "if its denial 'rest[s] upon an erroneous view of the law.'" *Id.* (quoting *Faile v. Upjohn Co.*, 988 F.2d 985, 986-87 (9th Cir. 1993)). The Ninth Circuit reviews any questions of law underlying a district court's decision *de novo*. *Jeff D. v. Kempthorne,* 365 F.3d 844, 850-51 (9th Cir. 1996). Waiver is one such question of law subject to *de novo* review. *In re Frontier Props., Inc.*, 879 F.2d 1358, 1362 (9th Cir. 1992); *see United States v. Johnson*, 67 F.3d 200, 202 n.3 (Fed. Cir. 1995).

This Court reviews a district court's interpretation of its own issued mandates *de novo. TransLogic Corp. v. Tele Eng'g, Inc.*, 194 F.3d 1334, 1334 (Fed. Cir. 1999); *see TecSec, Inc. v. Int'l Bus. Machs. Corp.*, 731 F.3d 1336, 1341 (Fed. Cir. 2013) ("[The Federal Circuit] interpret[s its] own mandate *de novo.*").

II. THE DISTRICT COURT ERRED IN DENYING ARTHREX'S MOTION TO REOPEN THE INFRINGEMENT JUDGMENT UNDER RULE 60(B)(6) IN LIGHT OF THE SUPREME COURT'S DECISION IN *LIMELIGHT NETWORKS*

A. Rule 60(B)(6) Is the Appropriate Vehicle to Raise the Divided Infringement Issue

Rule 60(b) permits district courts to reopen a final judgment or order for a number of grounds, including mistake, newly discovered evidence, and fraud. Fed. R. Civ. P. 60(b). Rule 60(b)(6) provides a catch-all, allowing a district court to reopen a final judgment for "any [] reason that justifies relief." *Id.* The rule reflects a court's inherent power to reopen its own judgments in the interest of justice "whenever such action is appropriate to accomplish justice." *Klapprott v. U.S.*, 335 U.S. 601, 615 (1949).

Although "the language of this residual clause is essentially boundless," the Supreme Court has clarified that it should be used in cases of extraordinary circumstances. *Twelve John Does v. District of Columbia*, 841 F.2d 1133, 1140 (D.C. Cir. 1988) (citing *Ackermann v. U.S.*, 340 U.S. 193, 202 (1950)). The Ninth Circuit has found that an intervening change of law impacting a final judgment can be such an extraordinary circumstance. *See Phelps*, 569 at 1132-33.

Courts look to several factors to determine whether a case presents "extraordinary circumstances" that warrant granting a motion under Rule 60(b)(6): (1) whether the intervening change in the law overruled an otherwise settled legal

precedent; (2) whether the petitioner was diligent in pursuing review of the issue; (3) whether the final judgment being challenged has caused one or more of the parties to change his position in reliance on that judgment; (4) whether there is delay between the finality of the judgment and the motion for Rule 60(b)(6) relief; (5) whether there is a close connection between the original and intervening decisions at issue in the rule 60(b) motion; and (6) whether relief from judgment would upset the delicate principles of comity governing the interaction between coordinate sovereign judicial systems. *Phelps,* 569 F.3d at 1135-40.

1. *Limelight Networks* Represents a Change in Law that Makes Rule 60(b)(6) Relief Appropriate

The recent change in law creates an extraordinary circumstance that warrants reopening the judgment. Under the current state of the law in *Limelight Networks*, there should be no question that Arthrex is entitled to judgment for its SutureTak products under its divided infringement defense (if Arthrex is permitted to raise the issue). The '557 patent has only method claims and no single entity practices every step of the claims for SutureTak. Arthrex attaches the suture to the anchor, and the surgeons practice the remaining steps. And there is no allegation that the surgeons, the accused direct infringers, direct and control Arthrex's actions when it pre-attaches the suture to the SutureTak anchors. Thus, this is the classic situation of divided infringement and there is no direct infringer who practices all

limitations of the claims. As a result, there can be no indirect infringement. *Limelight Networks*, 134 S. Ct. at 2118.[10]

But when this Court issued its decision in *S&N II*, the law on divided infringement was dramatically different. Just months before this Court issued that decision, it rendered its *en banc* ruling in *Akamai*, providing that "it is not necessary to prove that all the steps [of a claim] were committed by a single entity." *Akamai*, 692 F.3d at 1306.

Under *Akamai*, it is undisputed that Arthrex had no "divided infringement" defense. Arthrex could no longer deny liability because different entities (it and the surgeons) combined to practice all the steps of the claims. Thus, it comes as no surprise that this Court did not comment directly on the divided infringement issue (which Arthrex had raised as an alternative reason to uphold the judgment as it relates to SutureTak) when it issued its decision overturning the JMOLs in Arthrex's favor (issues unrelated to the divided infringement defense).

That is all that should be required for Rule 60(b) to be the proper vehicle for this Court to decide the divided infringement issue in Arthrex's favor (assuming, as we show below, that the district court's ruling that Arthrex waived its defense is in error). Arthrex had no defense under *Akamai* (the law when this Court decided *S&N II*) and it now has such a defense under *Limelight Networks*. *See Phelps*, 569

[10] Even the district court has never questioned these basic facts and the application of these facts to the law under either *Limelight Networks* or *BMC*.

F.3d at 1131 (Rule 60(b)(6) relief granted where petitioner would have prevailed if the new precedents where in effect during the earlier appeal).

In its Opposition to Arthrex's Rule 60(b) Motion below, S&N did not contest that *Limelight Networks* changed the law. Rather, it presented two arguments that this change in law did not matter to the outcome in this case. First, it argued that this Court decided the divided infringement arguments adversely to Arthrex based on the unrelated arguments presented in the parties' briefs in *S&N II*, rather than this Court's *en banc* decision in *Akamai*. A36317-19. Second, S&N argued that the decision in *Limelight Networks* did not matter because, except for the period of time from the Federal Circuit's *en banc* in *Akamai* until the Supreme Court's decision in *Limelight Networks*, the law was always clear that a single actor had to practice all limitations of the claim. A36293-98; A36303-304; A36308-312. Thus, the change of law had no impact on whether Arthrex could have raised the defense earlier. Neither argument has merit.

As for S&N's first argument, this Court never in said *S&N II* why it rejected Arthrex's position on divided infringement. What we *do know for certain*, however, is that *Akamai* had just been decided and that every panel of this Court, like every other appellate court, is required to follow *en banc* decisions. *E.g.*, *Koerner v. Grigas*, 328 F.3d 1039, 1046 (9th Cir. 2003) (finding "[a three-judge] panel lacks the authority to depart from the holding of an en banc opinion").

Since it is conceded that Arthrex had no divided infringement defense once *Akamai* was decided *en banc*, we know that *Akamai* provided an unquestioned basis to explain this Court action in *S&N II*. Since *Akamai* has now been reversed, this Court's decision in *S&N II* is not a bar to relief. *Gould, Inc. v. United States*, 67 F.3d 925, 930 (Fed. Cir. 1995) (explaining that, among other reasons, the mandate rule should not be applied when "controlling authority has since made a contrary decision of law applicable to the issues; or the earlier ruling was clearly erroneous and would work a manifest injustice").

On the other hand, it is nothing more than speculation whether the panel also considered the other arguments presented in the briefs. This Court has held that the mandate does not serve as a bar if the basis on the Court's decision is unclear. *TecSec, Inc. v. Int'l Business Machines Corp.*, 731 F.3d 1336, 1343 (Fed. Cir. 2013). In *TecSec*, the Court explained that where a district court's judgment was based on two independent grounds, and that judgment is summarily affirmed without analysis on either ground, the affirmance is not binding precedent (under either the mandate rule or collateral estoppel) for either ground "because it is impossible to glean which issues [were] decided." *Id.* This is more compelling circumstances than *TecSec* because we know for certain that a Federal Circuit law at the time (since overruled) precluded Arthrex's defense.

S&N's second argument, that the change of law in *Limelight Networks* did not matter because *Limelight Networks* merely reinstated the clear divided infringement law that was in existence throughout this case (A36293-98; A36303-304; A36308-312), ignores the import of the various precedents of this Court.

Without question, *On Demand* was this Court's most recent pronouncement of divided infringement when this case was first tried in 2007 (and when S&N contends that Arthrex was required to raise the divided infringement issue). In *On Demand*, this Court had approved a jury instruction sanctioning multiple entities combining to infringe without direction and control. 442 F.3d at 1344-45. As one commentator has recently observed, *On Demand* "seemingly permit[ed] liability any time the combined actions of two parties infringe a patent." Nathaniel Grow, *Joint Patent Infringement Following Akamai*, 51 Am. Bus. L.J. 71, 84 (2014).

BMC brought clarity to Federal Circuit law. As this Court explained in *Muniauction*, 532 F.3d at 1329, *On Demand* created confusion whether the standards for divided infringement had been relaxed and that *BMC* clarified the law. *Muniauction* does not stand alone. Even before *BMC* was decided, this Court, in *PharmaStem Therapeutics, Inc. v. ViaCell*, 491 F.3d 1342, 1358 n.1 (Fed. Cir. 2007), stated that the law on divided infringement was subject to considerable debate both in this Court and among the commentators and that this question was "squarely presented" in *BMC*, which was then pending before the Federal Circuit.

See also Grow, *supra*, at 26 (noting that "within the span of six months, two panels of the Federal Circuit had issued conflicting opinions, the first [in *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005)] apparently endorsing an agency-based standard for joint infringement, and the second [*On Demand*] seemingly permitting liability any time the combined actions of two parties infringed a patent."). Thus, contrary to S&N's assertion, the law was anything but clear.

2. The Other Factors also Weigh in Favor of Rule 60(b) Relief

A review of remaining five factors to be considered in a Rule 60(b)(6) motion confirms that it is the appropriate vehicle.

a. Diligence

Limelight Networks decision issued in June 2014. Arthrex has diligently requested relief, filing its Rule 60 and 62.1 motions early the next month and requesting expedited hearing of the motions to resolve the divided infringement issue in the most efficient way possible. A36233; A36237-39; A36241. Likewise, Arthrex immediately filed this appeal and again requested expedited briefing. A36664-65; Dkt. No. 12 at 5. In fact, Arthrex has pursued its divided infringement defense at every stage in this case once the defense became viable. *Supra* at 7-15.

b. Change in Position

None of the parties has changed their positions in reliance on the district court's 2013 judgment. The judgment is currently on appeal, and Arthrex obtained

a stay of enforcement of the resulting judgment under Fed. R. Civ. P. 62(d) by issuing a supersedeas bond. A36667; A36669-72. Thus, as in *Phelps*, neither party has undergone a change in position due to the district court's judgment, and there are no "past effects" of the judgment that would be disturbed if the judgment was reconsidered.

c. Delay

As in *Phelps*, this case has had a lengthy history and still remains ongoing. There is no delay at all, as final judgment was entered in late 2013, and that judgment is on appeal. Moreover, Arthrex sought to expedite consideration of this motion below as well as in this Court. A36233; A36237-39; A36241; Dkt. No. 12 at 5.

d. Close Connection

Phelps found there to be a close relationship between the intervening decision and the case at hand, because the intervening change in the law "directly overruled the decision for which reconsideration was sought." *Phelps*, 569 F.3d at 1139. Here too, *Limelight Networks* directly overruled the Federal Circuit precedent on divided infringement, and Arthrex's defense is predicated on the precise issue addressed in *Limelight Networks*.

e. Comity

Finally, there is no concern of comity surrounding the requested relief in this case. Given its intimate familiarity with the issues and evidence in the case, both

the district court and this Court can assess whether the intervening case law in *Limelight Networks* justifies the reopening of the judgment in the first place. *Cf. DeWeerth v. Baldinger*, 38 F.3d 1266, 1271 (2d Cir. 1994).

In sum, this is a strong case for Rule 60(b) relief. Ever since this Court made clear in *BMC* that divided infringement constitutes a defense to indirect infringement where, as here, no single entity practices each step of a method claim (itself or by direction and control of another), Arthrex has raised this defense wherever and whenever it could. *Supra* at 7-15. Despite these efforts, this Court has yet to issue a written opinion on the merits of Arthrex's position that the district court erred in refusing to allow to raise this defense (other than the motions panel that granted Arthrex's motion to stay the injunction and *agreed* with Arthrex's position). This Court did not decide the issue in *S&N I* because it decided the appeal in Arthrex's favor on other grounds. It did not discuss the issue in *S&N II* because the *en banc* decision in *Akamai* eliminated the defense. In essence, the parties are now in the same position as they were when this issue was last before this Court. It is now ripe for this Court to issue a written opinion, *for the first time*, whether Arthrex was entitled to raise the divided infringement defense when *BMC* was decided.

Review of this issue is extremely important because the vast majority of the $85 million in damages awarded by the jury ([redacted]

and a portion of the remaining $17 million in reasonable royalty damages) is attributable to the sales of Arthrex's SutureTak product, the product for which Arthrex has a divided infringement defense. Before Arthrex is required to pay such significant damages, fundamental fairness dictates that Arthrex is entitled to such review, as the purpose of Rule 60(b)(6) to prevent such unfairness. Should this Court agree that Arthrex can raise its "divided infringement" defense (*see infra* at 30-42), the Court should grant relief under Rule 60(b) and enter judgment for Arthrex for its SutureTak products.

B. The District Court's Refusal to Allow Arthrex to Raise Its Divided Infringement Defense Was Error

When the district court first prevented Arthrex from raising its divided infringement defense, this Court had just decided *BMC*, which ended the confusion caused by *On Demand*. Thus, unlike the law during the first trial when *On Demand* was this Court's latest pronouncement, *BMC* made it clear that Arthrex had a legitimate divided infringement defense because Arthrex performed that "attaching a suture to a member" method step, while the surgeons performed the remaining steps.

The district court has never challenged Arthrex's demonstration under *BMC*, and now under *Limelight Networks*, that Arthrex has a legitimate divided infringement defense, nor has it ever challenged Arthrex's description of this

Court's precedent. Instead, it steadfastly refused to allow Arthrex to assert the defense because it did not do so at the first trial.

Despite multiple opportunities to do so, it only once issued a written opinion explaining its reasoning why it refused to allow Arthrex to raise this defense. In its denial of Arthrex's summary judgment motion after the remand from *S&N I*, the district court gave two reasons for its decision. First, the district court found that this Court's mandate from *S&N I* precluded it from considering the issue. Second, it reaffirmed its view that Arthrex had waived the issue by not raising the defense at the first trial. As we show below, neither has merit.

1. The Mandate from *S&N I* Did Not Bar the District Court from Considering Arthrex's Defense

The mandate rule precludes a district court from considering only those issues that the appellate court actually decided. *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1364 (Fed. Cir. 2008); *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed. Cir. 1999). This includes those issues explicitly decided by the appeals court and those decided by "necessary implication." *Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951-52 (Fed. Cir. 1997).[11] The application of the

[11] The mandate rule does not prohibit a party from raising an issue that the appellate court did not address. *See, e.g., Sacco v. U.S.*, 452 F.3d 1305, 1308 (Fed. Cir. 2006) (holding that a prior opinion of a court "is not binding precedent on [a] point because the court did not address the issue"); *see also Brecht v. Abrahamson*, 507 U.S. 619, 631 (1993) (explaining that because the court had never squarely addressed an issue before, it was free to address it in the pending case).

mandate rule is reviewed by this Court *de novo*. *TecSec*, 731 F.3d at 1341 ("[The Federal Circuit] interpret[s its] own mandate *de novo*."); *TransLogic Corp.*, 194 F.3d at 1334.

Neither the district court nor S&N asserts that this Court explicitly decided the merits of the divided infringement issue in *S&N I*. Instead, the district court found that a ruling on Arthrex's divided infringement was necessary to the Federal Circuit's ruling because it remanded for a new trial on both the PushLock products and the SutureTak products. A13363-64. The district court reasoned that "if it had found in Arthrex's favor" on the divided infringement issue, it would have only remanded on PushLock (which did not raise the divided infringement issue). Instead, it remanded for a new trial on both products. *Id.*

That reasoning misses the real issue. The question is not did the Federal Circuit "decide the issue in Arthrex's favor." Rather, the question is whether the Federal Circuit decided the issue at all because the mandate rule only bars subsequent consideration if the issue was decided, actually or by necessity. *Engel*, 166 F.3d at 1383; *Laitram*, 115 F.3d at 951; *see also Amado*, 517 F.3d at 1359 ("An appellate mandate does not turn a district judge into a robot, mechanically carrying out orders that become inappropriate in light of subsequent factual discoveries or changes in the law.").

In this case, we do not have to guess at what this Court did and did not decide in *S&N I*. This Court reversed the infringement judgment against Arthrex because the district court's claim construction of resilience was in error. *S&N I*, 355 Fed. Appx. at 387. Beyond that, the Court specifically said that it did *not* consider Arthrex's other arguments.[12] The Court unambiguously stated:

> Because we have reversed the judgment of infringement against Arthrex, *it is not necessary to address Arthrex's additional arguments challenging that judgment*.

Id. at 389 (emphasis added). Arthrex's divided infringement position was, of course, an additional argument challenging the judgment. The Court told us that it did not consider such arguments. That should be the end of the matter.

The district court overcame this Court's unambiguous pronouncement by its observation that this Court remanded on both SutureTak and PushLock (rather than PushLock only). *Supra* at 32. Not only was the district court's reasoning inconsistent with this Court's statement that it did not consider Arthrex's additional arguments, it ignores the practical realities of appellate practice.

Rather than the district court's reasoning, the far more likely conclusion is that this Court did what it said and what appellate courts do all the time -- because it decides an appeal on one ground (the claim construction issue), it does not need to consider other grounds. In light of the Federal Circuit's specific statement that

[12] The Court, of course, did decide the invalidity issues that were presented as it was required to do. *Id.* at 387-89.

"it was not necessary" for it to decide Arthrex's other arguments against the judgment, the correct conclusion is that the Federal Circuit meant what it said and left the issue for the district court to deal with on remand.

This is particularly true where, as here, the only discussion on divided infringement from this Court was *in favor of* Arthrex's position when it granted Arthrex's emergency motion. *Supra* at 7-15. It is highly unlikely that this Court believed that Arthrex had "a strong likelihood of success" on the divided infringement issue early in 2009, and then later in the year decided Arthrex was wrong without a word of explanation. A30760-63; *S&N I*, 355 Fed. Appx. 384. That is not what happened. Rather, as the Court stated, "it was not necessary" for it to decide the issue.

2. Arthrex Did Not Waive Its Right to Raise Divided Infringement by Not Raising the Issue at the First Trial

In its summary judgment order, the district court based its finding that Arthrex waived the divided infringement issue on its assertion that "S&N never argued that the combined actions of Arthrex and the surgeons created joint liability for infringement, or even that the actions combined at all." Rather, according to the district court, S&N's theory was that the surgeons alone were the direct infringers. A13364-65.

That is *not* an accurate description of what happened at the first trial. To the contrary, *S&N* contended that the "attaching a suture to a member" method step

was met because *Arthrex, not the surgeons,* attached the suture to the anchor. *Supra* at 9. S&N was able to present its direct infringement proof by combining the actions of the surgeons and Arthrex because, at that time, *On Demand* was the state of the law, and S&N would have been entitled to the same jury instruction approved by the Federal Circuit in *On Demand* -- that the infringement could be met by showing that two different entities combined to meet all the limitations of the claims. 442 F.3d at 1344-45. In short, Arthrex had no legitimate "divided infringement" defense at the time of the first trial.

All that changed when the Federal Circuit decided *BMC*. As this Court explained, *On Demand* created confusion whether the direct infringement standard had been relaxed so that so that direction and control were not required. *BMC*, 498 F.3d at 1379-80; *Muniauction*, 532 F.3d at 1329. Thus, *BMC* "clarified the proper standard for whether a method claim is directly infringed by the combined actions of multiple parties." *Muniauction*, 532 F.3d at 1329; *see also, Pharmastem Therapeutics, Inc.*, 491 F.3d at 1382 n.1 (noting that there was "considerable debate" regarding the viability of the divided infringement defense and that this question was "squarely presented" in the then pending *BMC* appeal).

Just as this Court observed in *PharmaStem*, the Federal Circuit did squarely address this question in *BMC*. 491 F.3d at 1382 n.1. When it did (and made a ruling that would favor Arthrex), Arthrex appropriately raised the divided

infringement issue because it then had a defense. The district court committed legal error by refusing to allow Arthrex to raise its legitimate divided infringement defense. The motions panel of this Court was correct when it stated in *S&N I* that Arthrex had a "strong likelihood of success" on this issue. A30763. This Court should now endorse that ruling.

3. None of S&N's Other Arguments Changes this Result

S&N has raised two other reasons (neither of which was ever accepted by the district court) why it believed that Arthrex should not be allowed to raise a divided infringement defense. It contended that the "attaching a suture to a member" limitation was a structural limitation, only requiring that the suture be attached regardless of how it occurred. Second, it pointed to a surgical procedure called "plication" where the surgeon could remove the pre-attached suture and attach a different one. This procedure, as it relates to SutureTak, was long ago abandoned and S&N never had any evidence that any surgeon actually used a SutureTak that way.

a. "Attaching a Suture to a Member" Is Not a Structural Limitation

S&N contends that relief should be denied because this limitation is really a structural limitation, rather than a method step, that the district court made such a construction, and that Arthrex agreed. The express words of the claims, which

leave no doubt that "attaching a suture to a member" is a method step, provide a complete response to S&N's contention. For example, claim 1 states:

> 1. A method for anchoring in bone a member and attached suture, *the method comprising the steps of:*
>
> forming a hole in the bone;
>
> *attaching a suture to a member;*
>
> lodging the member within the hole by pressing the member with attached suture into the hole; and
>
> attaching tissue to the suture so that the tissue is secured against the bone.

A155 (emphasis added).[13]

Every now and then, the response to an argument is really that simple. This is one of those times. Of course, attaching the suture is a method step; it is exactly what the claim says. As a result, the single actor (a surgeon) must perform that (and every other) step for there to be a direct infringement.

Below (and previously in this Court) S&N has asserted nothing to detract from this plain language. S&N points to an embodiment in the '557 patent specification that describes an anchor with a suture embedded within and asserts that to construe the "attaching a suture" limitation as a method step would "exclude the preferred embodiment of the '557 patent." A36319-20; A19975-76. S&N is wrong. "Embedding" a suture is a manner of attaching it to the anchor. Moreover, the very embodiment to which S&N points also says that the suture can be

[13] Each claim of the '557 patent identifies this limitation as a method step.

"otherwise attached to" the anchor. A153 at col. 8, ll. 62-63. Thus, this "preferred embodiment" is not excluded.

S&N asserts that the prosecution history supports its contention that "attaching a suture to the member" is a structural limitation. S&N points to the discussion of the Freedland reference (A36320), but points to nothing where either it or the patent examiner stated that, despite the plain language of the claims, the step of "attaching a suture to a member" in the '557 claims was a structural limitation. The prosecution history, however, is anything but silent on this subject. On at least five occasions during its discussion of Freedland, S&N itself described the "attaching a suture to a member" as a step of the claimed method. A634, A637, A650-51, A656. Thus, far from supporting S&N's argument, the prosecution history contradicts it.[14]

Finally, S&N points to a statement made by the district court that "the suture is attached to the anchor itself," as supporting its assertion that the Court construed

[14] S&N also asserts that the patent examiner and the Board of Appeals understood the "attaching a suture to the member" limitation was not a method step. A36320. S&N cannot cite to where the examiner actually stated this. Instead, S&N points to the examiner's use of the Freedland reference, which, according to S&N, discloses a pre-attached suture and not a step of attaching the suture, to anticipate this claim limitation. *Id.* But even if S&N's description about Freedland were correct, it does not help S&N. Assuming Freedland did disclose only an apparatus, an apparatus disclosed in a prior art reference can anticipate a method step. *See, e.g., In re King*, 801 F.2d 1324, 1326-27 (Fed. Cir. 1986); *Respironics, Inc. v. Invacare Corp.*, 437 Fed. Appx. 917, 920-21 (Fed. Cir. 2011) (finding that article disclosing apparatus anticipates method claim).

"attaching a suture" as a structural limitation (and that Arthrex agreed with this construction). A36299-6300; A36319; A33468; A19975-76. But when the district court stated this, it was instructing the jury that the eyelet on Arthrex's anchors, which is the location through which the suture is threaded, is "part of 'the anchor itself.'" A36639-640. Thus, this was a comment on the "member" limitation (that the molded-in eyelet was part of the member) and *not* that the "attaching a suture" method step is actually a structural limitation. For the same reasons, Arthrex never agreed that the "attaching the suture to the member" method step was somehow converted into a structural limitation.

b. S&N's Reference to the Plication Method Does Not Provide a Reason to Deny Arthrex's Motion

As a last ditch argument, S&N has contended that there is evidence that surgeons replace the replace the pre-attached suture of the SutureTak anchors with other sutures. This contention, which at best can be described as a "tail wagging the dog" argument, refers to an obsolete device called a "plication driver" where a surgeon using this device together with a SutureTak, if he or she so chose, could remove the pre-attached suture and replace it with another suture. Even if this were a valid argument, it would at most impact a small fraction of 1% of the SutureTak sales.[15]

15 [redacted]

While S&N has claimed that surgeons replace the suture and attach another one, it presented no evidence establishing that any surgeon used the plication device to do so. *See Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). In fact, the only evidence of record of the surgeon use of plication establishes the opposite. When Dr. Stephen Burkhart was deposed, he testified that there are different ways to do the plication surgical technique and that when he practices that technique, he uses the suture that already attached by Arthrex. He concluded his testimony as follows:

> Q. So you've done plication where you – you've used the suture that was already attached by Arthrex, right?
>
> A. That – that's how I do it, yes.

A9276-77.

The irony of S&N's plication argument is that it assumes that Arthrex is correct that it *is* entitled to raise a divided infringement defense. The most that could be said of S&N's argument is that, should this judgment be reopened, this Court should not enter judgment *against S&N*. That, however, is incorrect because, as explained above, S&N has no evidence that surgeon actually replace sutures. *Supra at* 39-40.

[redacted] Since the plication driver is a single-use devise (one that is used in only a single surgery) (A13356), [redacted]

But even if there were something to S&N's argument, what is certain is that the damages award against Arthrex could not stand. If there were validity to S&N's position, it would only be entitled to a royalty on the fraction of 1% of SutureTak anchors (if any at all) where the surgeon did remove the pre-attached suture and attach a different suture, an amount that likely would be at most [redacted]

The damage award attributable to SutureTak, however, ([redacted] and part of the $17 million awarded as reasonable royalties, *supra* at 12), was based on the sale of each and every SutureTak anchor accused in this case. If Arthrex is correct that under the current law there is no liability for SutureTak unless the surgeons actually attach the suture to the anchor (and Arthrex promotes such a technique), then virtually all of those damages would disappear even if S&N were correct about some aspect of its "plication" argument.[16] To allow S&N to retain such a large and inappropriate damage award

[16] At the first trial, when S&N had to meet "the attaching a suture to a member" limitation, it did not say a word about this plication issue to the jury, and it did not put forth any evidence of a single surgeon replacing the pre-attached SutureTak suture by another suture.

This omission is telling. If it had such evidence, it would have permitted S&N to present evidence that the surgeon performed every step of the claims (S&N's view of what it did) because it could have shown that the surgeon, rather than Arthrex, performed the method step of "attaching a suture to a member." It did not pursue this avenue because any damages would have been extremely limited. Having taken discovery, S&N knew that an extremely small amount of sales of the SutureTak product could theoretically involve the plication method.

would be an injustice, exactly the type of situation that Rule 60(b) is designed to prevent.

CONCLUSION

For all the foregoing reasons, this Court should reverse the district court's failure to grant Rule 60(b)(6) relief, enter judgment for Arthrex that it did not indirectly infringe the '557 patent in connection with its sale and activities in connection with its SutureTak products, and remand to the district court for further proceedings.

Dated: September 15, 2014

By: /s/ Charles W. Saber

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Supra at 39-41. That is why it chose a different route at trial, arguing that the method claims were infringed even though Arthrex itself performed that step.

ADDENDUM

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ADDENDUM A

Seutter, Alan

From: info@ord.uscourts.gov
Sent: Friday, August 15, 2014 1:15 PM
To: nobody@ord.uscourts.gov
Subject: Activity in Case 3:04-cv-00029-MO Smith & Nephew Incorporated et al v. Arthrex, Incorporated Order on Motion - Miscellaneous

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U.S. District Court

District of Oregon

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Case Number: 3:04-cv-00029-MO
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Document Number: 1161(No document attached)

Docket Text:
ORDER: DENYING Motion and Memorandum For Indicative Ruling Under Fed. R. Civ. P. 62.1. [1151]; DENYING Motion and Memorandum To Reopen The Judgment Under Rule 60(B) [1152]. Ordered by Judge Michael W. Mosman. (dls)

3:04-cv-00029-MO Notice has been electronically mailed to:

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ADDENDUM B

US005601557A

United States Patent [19]

Hayhurst

[11] **Patent Number: 5,601,557**

[45] **Date of Patent: Feb. 11, 1997**

[54] **ANCHORING AND MANIPULATING TISSUE**

[76] Inventor: **John O. Hayhurst**, 14751 SE. Wanda Dr., Milwaukie, Oreg. 97222

[21] Appl. No.: **715,113**

[22] Filed: **Jun. 12, 1991**

Related U.S. Application Data

[60] Division of Ser. No. 192,813, Apr. 20, 1988, abandoned, which is a continuation-in-part of Ser. No. 848,341, Apr. 4, 1986, Pat. No. 4,741,330, which is a continuation of Ser. No. 496,116, May 19, 1983, abandoned, which is a continuation-in-part of Ser. No. 380,043, May 20, 1982, abandoned.

[51] **Int. Cl.**[6] **A61B 17/56**; A61B 17/04

[52] **U.S. Cl.** **606/72**; 606/144

[58] **Field of Search** 606/90, 88, 103, 606/144, 146, 148, 149, 150, 151, 152, 153, 155–157, 216, 217, 222–226, 232, 233, 75, 72, 73, 74, 220; 411/340, 508–511, 904

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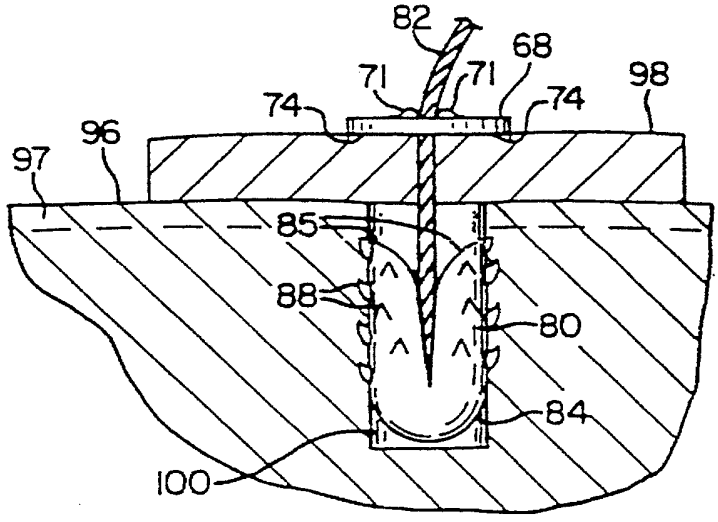
Primary Examiner—Michael A. Brown

Attorney, Agent, or Firm—Klarquist Sparkman Campbell Leigh & Whinston, LLP

[57] **ABSTRACT**

A method whereby an anchor member is configured to provide anchorage of its attached suture within a hole drilled in a bone.

7 Claims, 3 Drawing Sheets



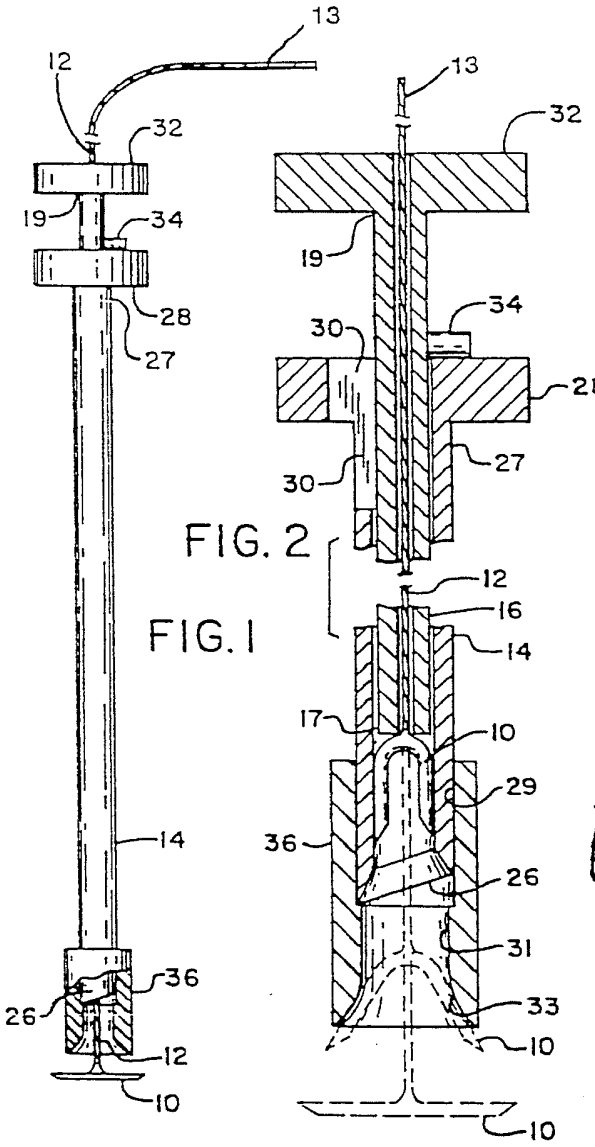


FIG. 1

FIG. 2

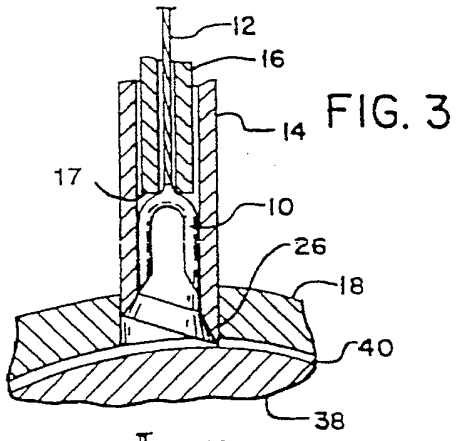


FIG. 3

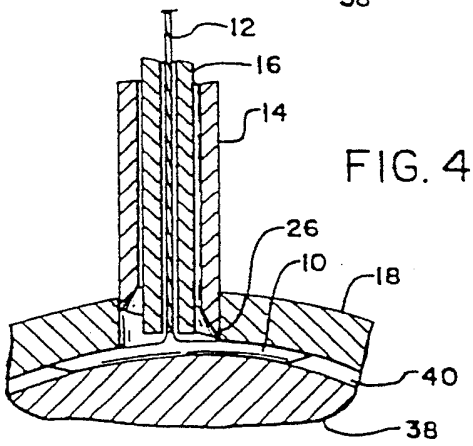


FIG. 4

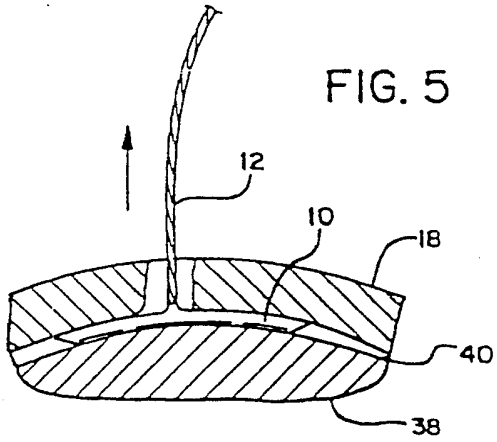


FIG. 5

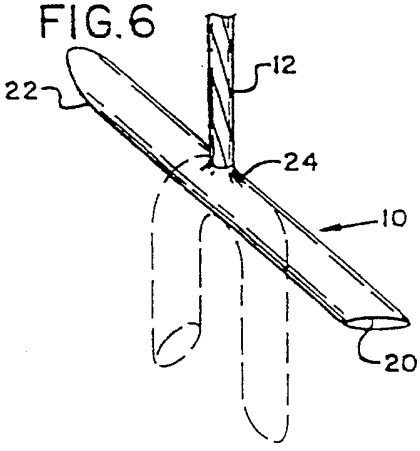


FIG. 6

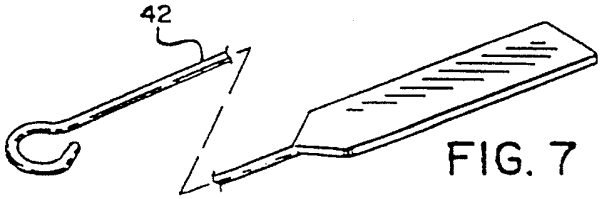
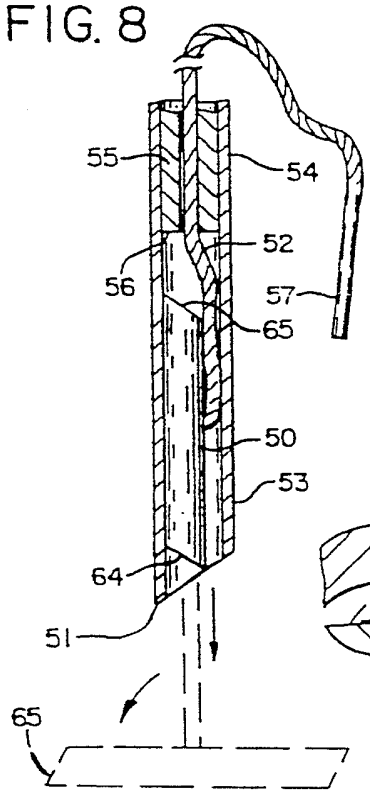


FIG. 7

FIG. 8



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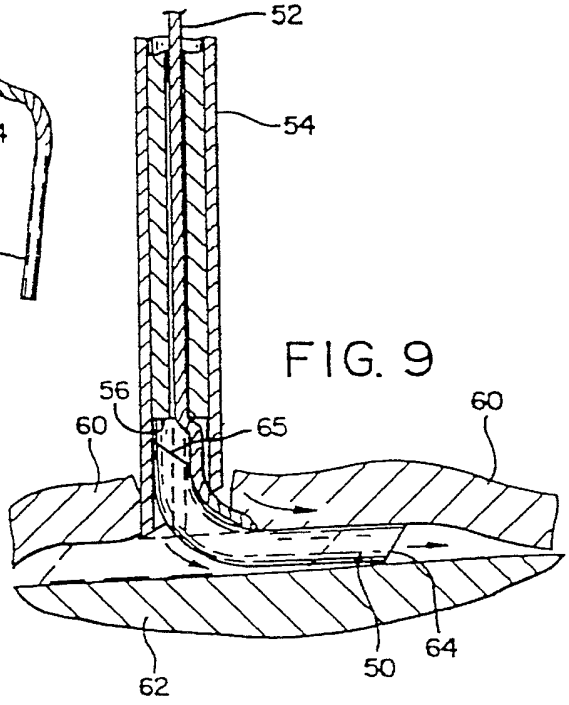


FIG. 12

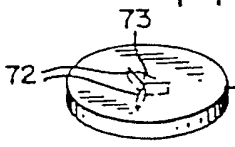


FIG. 11

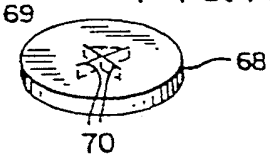
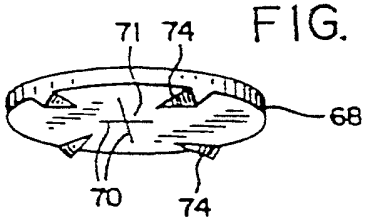


FIG. 10



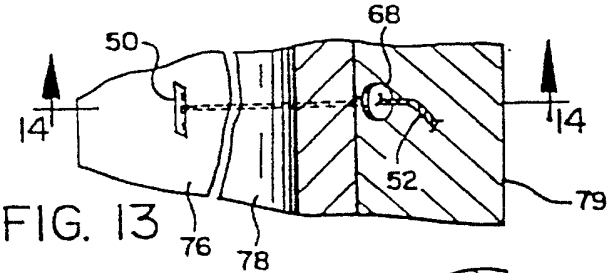


FIG. 13

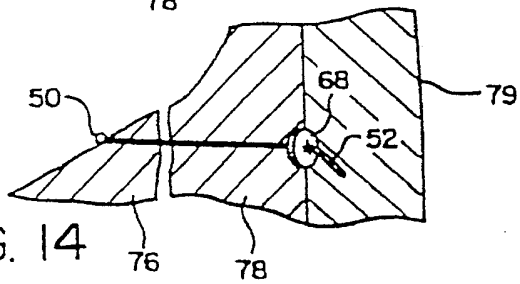


FIG. 14

FIG. 15

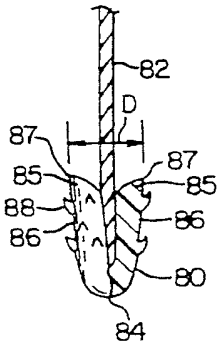


FIG. 16

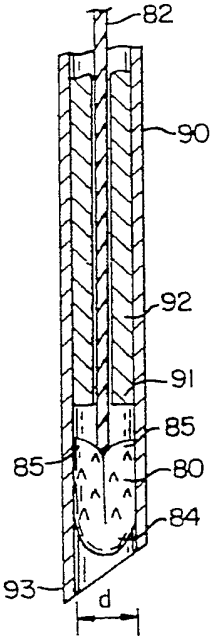


FIG. 17

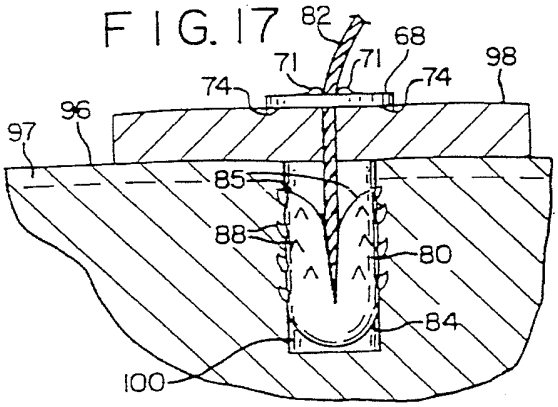


FIG. 18

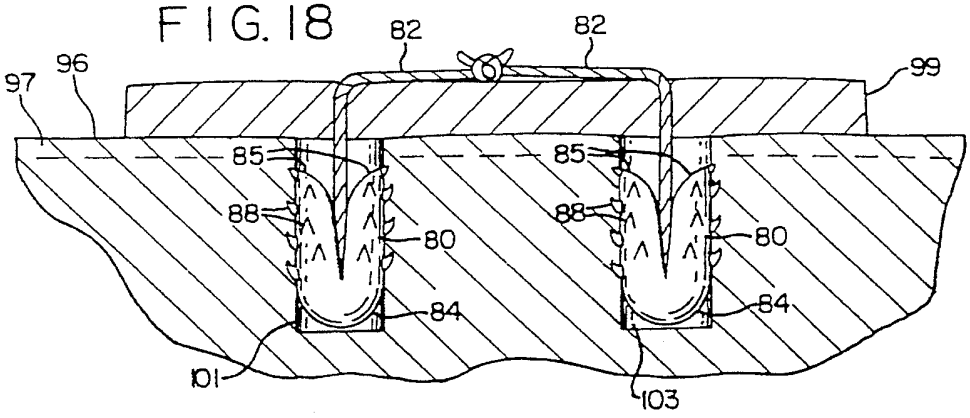


FIG. 19

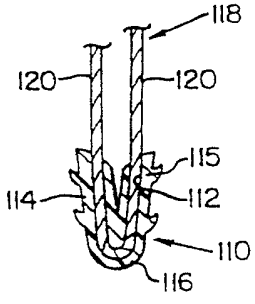


FIG. 20

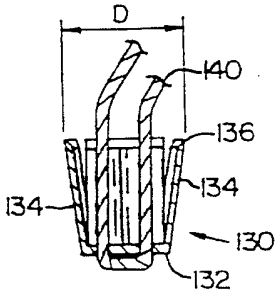
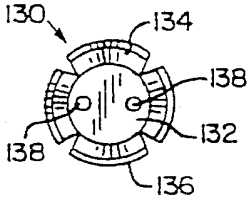


FIG. 21



ANCHORING AND MANIPULATING TISSUE

This application is a divisional of application No. 07/192,813, filed Apr. 20, 1988, now abandoned, which was a continuation-in-part of application No. 06/848,341, filed Apr. 4, 1986, now U.S. Pat. No. 4,741,330, which is a continuation of Application Ser. No. 07/496,116, filed May 19, 1993, now abandoned, which is a continuation-in-part of Application Ser. No. 07/380,043, filed May 20, 1982, now abandoned.

BACKGROUND INFORMATION

This invention relates to an apparatus and method for manipulating and anchoring cartilage and similar fibrous tissue within a joint.

Conventional medical clamps have certain disadvantages when used for manipulating cartilage or other tissue within a joint during arthroscopic surgery. Primarily, the clamps have a tendency to slip off the cartilage. Additionally, the size of the clamps in relation to the relatively small space within the joints makes it difficult to maneuver other surgical instruments, such as a scalpel or arthroscope, within the confined space of the joint. Such clamps can also interfere with the view of the inside of the joint afforded by the arthroscope. Since the clamps must be introduced into the joint through an incision, they are limited in their range of manipulation by the location of the incision. In order to apply a desired directional traction to the cartilage, it may be necessary to release the clamp from the cartilage, reintroduce the clamp through another incision, and reclamp the cartilage.

It is often necessary to repair torn fibrous tissue, such as a ligament or tendon, or reattach such tissue to bone. While in some instances it is possible to insert two needles into the joint and then thread both of them with a suture to form a loop to reattach torn parts of fibrous tissue, that procedure is undesirable because it is complex and time-consuming. The alternative of more radical arthrotomy is also undesirable because of the increased amount of trauma and resultant increased morbidity encountered in the use of such a procedure.

As is explained in the following summary and description, the present invention provides a relatively compact and easy to use apparatus for manipulating cartilage and other fibrous tissue, and for anchoring the tissue to other tissue or to bone. Some technical references that may be of general interest are as follows: Allen, U.S. Pat. No. 3,699,969; Shein, U.S. Pat. No. 3,527,223; Woo, U.S. Pat. No. 3,943,932; Almen, U.S. Pat. No. 3,500,820; Johnson et al., U.S. Pat. No. 3,871,368; and Smith, U.S. Pat. No. 4,243,037. None of these references discloses a method or apparatus suitable for manipulating fibrous tissue during arthroscopic surgery, or for effectively reattaching fibrous tissue to bone or to other fibrous tissue.

SUMMARY OF THE INVENTION

The aforementioned problems associated with use of conventional medical clamps for manipulating tissue are overcome by the present invention, which provides an apparatus and an associated method for manipulating and anchoring tissue during arthroscopic surgery. The apparatus provides adequate fixation of the tissue during such surgery and minimally interferes with the use of other instruments within the joint.

The apparatus particularly comprises an elongated anchor member having a suture attached proximate the midpoint of its length. The anchor member is inserted through the tissue with the suture extending therefrom to provide a mechanism for manipulating the tissue within the joint. The end faces of the anchor may be slanted to facilitate movement of the anchor member through the tissue.

The preferred means of inserting the anchor member includes a hollow needle having a sharp tip and an open butt. A hollow tube of equal or greater length than the needle slides within the needle. A limiting mechanism is provided at the butt of the needle and at the corresponding portion of the hollow tube to selectively position the tube within the needle so that the tube does not extend outwardly beyond the tip of the needle.

The anchor member is located within the tip of the hollow needle in either a deformed U shape, or in its normal, substantially straight shape. The suture extends from the anchor member through the bore of the tube.

A removable shield fits over the tip of the needle to prevent the sharp tip from cutting the suture or the anchor member during the process of inserting the anchor member into the hollow needle.

With the anchor member located within the tip of the needle, the needle tip is inserted into a joint during a surgical procedure. The needle tip pierces the tissue to be anchored and passes substantially through the tissue. The limiting mechanism is manipulated so that the tube may be pushed forward to the tip of the needle, thereby expelling the anchor member from the tip of the needle into or behind the piece of tissue to be anchored. As the anchor member is expelled from the tip of the needle it assumes an orientation generally perpendicular to the length of the suture. The needle and tube are then removed from the joint, leaving the suture extending through the tissue and out of the joint. The tissue is manipulated by the application of tension on the suture.

If it is desirable to push the tissue, the suture may be rethreaded or left threaded in the tube and the tissue may then be securely held between the tube and the anchor member by applying tension to the suture. If it is desirable to control the tissue from a different angle, or through a different incision, a hook-ended instrument may be passed through another incision to hook the suture and pull the tissue. It will be apparent that moving the tissue in this manner is possible without detaching the anchor member from the tissue. If necessary, the tissue may be removed from the joint by tension on the suture once the tissue has been surgically freed from the joint.

It is often desirable to permanently reattach to bone fibrous tissue, such as tendons or ligaments. An alternative embodiment of a tissue anchoring apparatus is provided for that purpose. More particularly, the apparatus of this embodiment includes a deformable anchor member that has a base and at least two legs. Each leg is attached to the base and extends therefrom to terminate in an outer end. A suture is attached to the base of the anchor member. The anchor member is formed of resilient material for urging the anchor member into a relaxed position wherein the ends of the legs are spaced apart a maximum distance. The anchor member is deformable into a deformed position wherein the ends of the legs are spaced apart a minimum distance that is less than the maximum distance.

While in the deformed position, the anchor member is insertable into a hole that is drilled into the bone at the location the tissue is to be attached to the bone. The hole has a diameter that is less than the maximum distance between

the ends of the anchor member legs. Consequently, upon insertion of the anchor member into the hole, the ends of the anchor member legs bear upon the bone within the hole, and the suture extends from the hole. Whenever tension is applied to the suture, the ends of the legs dig into the bone and resist removal of the anchor member from the hole.

With the anchor member anchored in the hole, the suture is available for securing the tissue to the bone. One way of using the suture to secure the tissue to the bone is to attach a retainer to the suture for pressing the tissue against the bone. The retainer includes resilient suture-engaging edges and corners, and is slidable along the suture in one direction, but grips the suture to resist sliding in the opposite direction. The retainer thereby holds tissue against the bone during healing so that the tissue will properly reattach to the bone.

To avoid prolonged irritation of surrounding tissues, the anchor member, suture, and retainer of the present invention may be made of material that is gradually absorbable by the body.

The foregoing and other features of the invention will be more readily understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view of an apparatus for manipulating and anchoring tissue according to the present invention, with a portion of the apparatus sectionally cut away.

FIG. **2** is a sectional elevational view of the apparatus shown in FIG. **1**, illustrating the manner of deformably lodging an anchor member within the tip of a hollow needle.

FIG. **3** is a fragmentary, sectional elevational view of the apparatus of FIG. **1**, showing the apparatus piercing cartilage.

FIG. **4** is a fragmentary, sectional elevational view of the apparatus of FIG. **1**, illustrating the manner of expelling the anchor member between cartilage and bone.

FIG. **5** is a sectional elevational view of the apparatus of FIG. **1**, showing cartilage secured by the anchor member and suture components of the apparatus.

FIG. **6** is an enlarged perspective view of the anchor member and suture, showing the normal and deformed configuration of the anchor member.

FIG. **7** is a foreshortened perspective view of a hook-ended instrument usable with the apparatus of FIG. **1**.

FIG. **8** is a sectional elevational view of an apparatus for manipulating and anchoring tissue, illustrating an alternative manner of lodging the anchor member within the tip of the needle.

FIG. **9** is a sectional elevational view of the apparatus shown in FIG. **8**, illustrating expulsion of the anchor member from the tip of the needle.

FIG. **10** is a perspective view of the inner surface and an edge of a retainer used in association with the suture and the anchor member for securing tissue to bone or to other tissue.

FIG. **11** is a perspective view of the outer surface and an edge of the retainer shown in FIG. **10**.

FIG. **12** is a perspective view of an alternative retainer.

FIG. **13** illustrates a portion of a joint in which the anchor member, suture, and retainer are used to connect and retain a piece of cartilage in position against another piece of cartilage from which it had been torn.

FIG. **14** is a sectional view taken along line **14**—**14** of FIG. **13**.

FIG. **15** is a side elevational view, partly in section, of an anchor member and suture that can be anchored to a bone.

FIG. **16** is a sectional elevational view of the anchor member and suture of FIG. **15**, positioned within the preferred mechanism for inserting the anchor member into a hole in a bone.

FIG. **17** is a sectional elevational view showing the anchor member of FIG. **16** anchored within a hole in a bone and used, in conjunction with the suture and a retainer, to hold tissue against the bone.

FIG. **18** is a sectional elevational view showing an alternative method of using an anchor member and suture to hold tissue against the bone.

FIG. **19** is a side cross-sectional view of an alternative embodiment of an anchor member that has a hole formed therethrough to permit a suture to be looped through it.

FIG. **20** is a cross-sectional view of another alternative embodiment of an anchor member than can be anchored to a bone.

FIG. **21** is a top view of the anchor member of FIG. **20**.

DESCRIPTION OF PREFERRED EMBODIMENTS

One preferred embodiment of the present invention, shown assembled in FIGS. **1** and **2**, provides a resiliently deformable anchor member **10**, which is attached to a suture **12** and adapted to fit deformably within the tip **26** of a hollow needle **14**. A hollow tube **16**, also adapted to fit within the needle **14**, is used to expel the anchor member from the tip **26** of the needle after the needle has pierced a piece of fibrous tissue, such as the cartilage **18**, as shown in FIGS. **3** and **4**. Once expelled between the cartilage **18** and bone **38**, the anchor member resiliently resumes its normal shape, as shown in FIG. **5**. The anchor member of the invention might also be used to secure ligament or tendon, as will be described hereinafter, and the term tissue will be broadly used herein to encompass cartilage, tendons, ligaments and similar tissue.

The anchor member **10**, shown in perspective view of FIG. **6**, is an elongated cylindrical member. The anchor member **10** has end faces **20** and **22** at the respective extremities thereof. The end faces **20** and **22** are slanted relative to the longitudinal axis of the anchor member and preferably lie in respective planes that intersect one another. The suture **12** is attached to the anchor member **10** at a location **24** between the end faces **20** and **22**. The suture **12** may be attached to the anchor member **10** during formation of the anchor member.

The anchor member **10** is preferably comprised of a resilient material such as a plastic. As a result, the anchor member is capable of being deformed from its relaxed, straight shape into a U-shape as shown in broken line in FIG. **6**. Although the anchor member is shown to have a circular cross section, other cross-sectional shapes could be utilized without departing from the principles of this invention.

The anchor member **10** is formed with sufficient rigidity to cause it to resist deformation under moderate pressure, but not so rigid as to prohibit the U-shaped deformation when the anchor member is lodged within the needle as shown in FIG. **2** and **3**. The material comprising the anchor member has sufficient elasticity to restore the anchor member substantially to its relaxed, straight configuration shown in FIGS. **1**, **4**, **5** and **6**.

The needle **14** shown in FIGS. **1** and **2** has a hollow cylindrical shape with a sharp-edged open tip **26**, an open

butt **27**, and a bore extending longitudinally therethrough from the tip **26** to the butt **27**. The sharp tip **26** is beveled to create a sharp edge at its outer circumference and is thereby adapted to pierce and penetrate tissue. Alternatively, the sharp tip **26** could be beveled to create a sharp edge at its inner circumference.

An annular collar **28**, which includes an open keyway **30** formed therein, encircles the butt of the needle. The keyway extends a short distance toward the needle tip through the cylindrical wall of the needle as shown in FIG. **2**.

The hollow tube **16**, which is at least as long as the needle **14**, and has an elongated cylindrical shape with an open tip **17** and an open butt **19**, is adapted to slide within the hollow needle. The tube **16** has an interior bore diameter large enough to receive the suture **12** therethrough so that the free end **13** of the suture extends from the open butt **19** of the tube. The tube **16** has an annular flange **32** encircling the butt **19** thereof to prevent the tube, when pushed toward the needle tip **26**, from protruding more than a predetermined distance beyond the tip. The tube is preferably such a length that when the flange **32** is positioned immediately adjacent the collar **28**, the tip **17** of the tube is proximate the needle tip **26**, as shown in FIG. **4**.

A limiting mechanism for controlling movement of the tube **16** is provided in the form of a key **34** that is mounted on the outer cylindrical wall of the tube **16**. The key **34** is adapted to mate with the keyway **30** associated with the needle **14**. The key **34** will prevent the tip **17** of the tube **16** from moving proximal to the tip **26** of the needle **14** unless the key **34** is aligned with the keyway **30**. This alignment is accomplished by rotation of the tube **16** within the needle **14**. If the tube **16** is of the aforementioned preferred length, the key **34** should be located close enough to the tip **17** of the tube **16** to permit the anchor member **10** to be fully drawn into the needle tip **26** when the tube is positioned inside the needle with the key and keyway out of alignment, as shown in FIGS. **2** and **3**. As will be apparent, the keyway **30** should be of sufficient length to allow the flange **32** to contact the collar **28** when the key **34** is positioned in the keyway **30**. It should be recognized that, while a aforedescribed key and keyway arrangement is believed to be particularly suitable, other mechanisms for limiting the movement of the tube **16** within the needle **14** could be utilized without departing from the principles of this invention.

As shown in FIGS. **1** and **2**, a shield **36** having a generally cylindrical shape with open ends is adapted to fit removably on the sharp needle tip **26**. The inner walls of the shield have three distinct sections: an upper section **29**, an intermediate section **31**, and a lower section **33**. The upper section **29** is cylindrical and has an inner diameter substantially equal to the outer diameter of the needle tip **26** so as to permit the shield to be mounted over the tip **26**. The intermediate section **31** is cylindrical and has an inner diameter slightly smaller than the outer diameter of the needle tip **26**, to shield the anchor member from the sharp edge of the needle tip **26**. The lower section **33** has a bell-like flared shape to encourage appropriate deformation of the anchor member **10** as it is drawn into the needle tip **26** as shown in FIG. **2**.

Prior to use, the apparatus is first assembled as shown in FIGS. **1** and **2**, the shield **36** being mounted upon the tip **26** prior to the suture **12** being threaded through the tube **16** so that the free end **13** protrudes out the butt end **19** of the tube. Tension on the free end **13** of the suture **12** will pull the anchor member **10** into the needle tip **26** as shown in FIG. **2**, the inner surface of the bell-shaped lower section **33** of the shield guiding the anchor member into the appropriate U-shape, the anchor member being protected from the sharp tip by the shield **36**.

The tube **16** is axially positioned within the needle with the key **34** abutting the collar **28** so that there is appropriate space for the anchor member to lodge deformably within the needle tip **26**. Positioning the tube **16** within the needle as shown in FIGS. **1** and **2** is not necessary prior to introducing the free end **13** of the suture **12** into and through the bore of the needle **14**, but having the tube so positioned when the anchor member **10** is drawn into the tip **26** is helpful to ensure that the anchor member **10** is not positioned an unnecessary distance from the needle tip **26**. Once the anchor member **10** is deformably lodged in the tip **26**, the shield **36** may be removed.

The assembled apparatus may then be introduced into the joint of a patient, either through an incision or by using the needle tip **26** to pierce the skin and surrounding tissue. The tip **26** of the needle **14** is thereafter used to pierce the cartilage **18** which is to be manipulated or anchored, as shown in FIG. **3**.

One the tip **26** has pierced the cartilage **18**, the tube **16** may be axially rotated within the needle **14** so that the key **34** aligns with the keyway **30**. The tube **16** may then be pushed toward the tip **26** of the needle **14**, the key **34** entering the keyway **30**, and the tip **17** of the tube **16** expelling the anchor member **10** from the needle tip **26** as shown in FIG. **4**. As the anchor member **10** is pushed from the needle tip **26**, it resumes its normal elongated shape. Where the cartilage **18** is very near bone **38**, the slanted end faces **20**, **22** of the anchor member facilitate movement of the longitudinal extremities of the anchor member through the space **40** between the bone **38** and cartilage **18**.

Once the anchor member **10** has generally resumed its normal elongated shape behind the cartilage **18**, the needle **14** and the tube **16** may be withdrawn from the joint, allowing the cartilage **18** to partially collapse around the anchor member **10** and suture **12** as shown in FIG. **5**. The suture **12** is now anchored to the cartilage **18**, and the cartilage may be securely held and manipulated by tension on the suture **12** to facilitate further surgical procedures on and around the cartilage.

The relatively small size of the suture **12** allows virtually unobstructed vision of the interior of the joint through an arthroscope, and also permits the insertion of other surgical instruments, such as an arthroscope or scalpel, through the same incision as the suture. Due to the flexibility of the suture **12**, tension may be applied from many directions as dictated by the needs of the surgical process. Further control of the cartilage **18** is available by rethreading the suture **12** through the tube **16** and applying tension to the suture, thereby effectively clamping the cartilage **18** between the anchor member **10** and the tip **17** of the tube **16**, and allowing the cartilage to be pushed, rather than pulled, into a desired position.

A hook-ended instrument **42**, shown in FIG. **7**, may be used to achieve even greater maneuverability of the anchored cartilage **18** by introducing the instrument **42** into the joint through a separate incision, capturing the suture **12** in the hooked end of the instrument, and drawing the suture **12** out of the joint through such other incision. The cartilage may then be manipulated and controlled in the manner described above, through a different incision, without detaching the anchor member **10** from the anchor cartilage **18**.

If necessary, the anchored cartilage **18** may be surgically freed, and removed from the joint by tension on the suture **12**.

Referring now to FIGS. **8** and **9**, an anchor member **50**, which is similar to the anchor member **10** described above, has fixedly attached thereto a suture **52**. The anchor member **50** is held within the tip **53** of a hollow needle **54**, ahead of the tip **56** of a hollow tube **55**. The edge of the hollow needle **54** at the tip **53** is formed in a plane that is slanted relative to the longitudinal axis of the needle, thereby to form a sharp leading edge **51** for piercing tissue. The free end **57** of the suture **52** extends from the hollow tube **55**.

As shown in FIGS. **8** and **9**, the anchor member **50** may be used in essentially the same fashion as is the anchor member **10**, with the hollow needle **54** piercing a piece of fibrous tissue, such as cartilage **60**. The anchor member **50** is expelled from the tip **53** of the hollow needle **54** as the hollow tube **55** is slid toward the tip **53** of the hollow needle **54**. The anchor member **50** thereafter assumes a position between the cartilage **60** and a bone **62**, where it extends generally perpendicular to the suture **52**. The slanted end faces **64**, **65** of the anchor member **50** assist in directing the anchor member **50** to this position. Once the anchor member **50** has been expelled from the needle **54**, the suture **52** is pulled outwardly to move the anchor member **50** to the position shown in broken line in FIG. **9**, where it extends laterally along the lower surface of the cartilage **60**.

It is noteworthy that the anchor member **50** depicted in FIGS. **8** and **9** may be formed of substantially rigid material. A rigid anchor member can be inserted into the space between the cartilage and bone by moving the needle **54** so that it is inclined to the bone surface and then expelling the anchor member from the needle.

A rigid anchor member may be lodged within cartilage or other tissue (i.e., as opposed to being inserted between cartilage and bone) by expelling the anchor member substantially straight into the tissue and pulling on the suture. Because the suture is attached between the ends of the anchor member, tension on the suture tends to rotate the anchor member into a position substantially perpendicular to the suture, thereby causing the anchor member to become firmly lodged within the tissue. In this regard, rotational movement of the anchor member **50** into a position substantially perpendicular to the suture **52** most readily occurs when the end face **65** that last enters the tissue is slanted so that a force applied perpendicular to that surface (that force being a component of the reaction force of the tissue against the surface **65** as tension is applied to the suture of the expelled anchor member) tends to move that face **65** of the anchor member **50** away from the suture **52**. This preferred slanting of the end face **65** is shown in FIGS. **8** and **9**.

Referring now to FIGS. **10–14**, retainer devices **68** and **69**, each having a pair of generally parallel surfaces, are made of resilient material and have slits **70** and **72**, respectively, which intersect near the central points of the parallel surfaces, defining pointed corner flaps **71** and **73**, respectively. The retainers **68** and **69** are preferably circular because the circular shape may reduce the possibility of irritation of surrounding tissue. It will be understood, however, that this shape is a matter of choice and that other shapes would also be acceptable.

Raised points **74** are provided on the inner surface of the retainer **68** to bear against tissue, and to assist in immobilizing the tissue while the anchor member is in use. In many instances, however, the raised points **74** will not be required and a flat inner surface will suffice. The following discussion of retainer use is directed to the anchor member **50** of FIG. **8**; however, it is understood that the discussion applies to all embodiments of the anchor member described herein.

The retainer **68** (or retainer **69**) may be used in conjunction with the anchor member **50** by inserting the free end **57** of the suture through the retainer at the intersection of the slits **70** after the hollow needle and hollow tube have been withdrawn from around the suture. When the suture **52** is inserted through the retainer **68**, the flaps **71** that are defined between adjacent slits **70** are resiliently deformed toward the direction of movement of the suture therethrough. Thereafter, the flaps wedge against the suture **52** and resist withdrawal of the suture through the slits. By applying tension to the suture **52** (see FIGS. **13** and **14**) and urging the retainer **68** along the suture to the surface of cartilage **76** from which the suture extends, the retainer may be used to maintain tension in the suture, thereby holding a loose piece of cartilage **76** against the stable piece of cartilage **78** from which the loose piece of cartilage **76** had been torn or fractured.

The anchor member **50**, suture **52**, and retainer **68** may be left permanently in the joint to retain the torn cartilage **76** in its proper location against the stable cartilage **78**, with the retainer **68** resting against the outside of the stable cartilage **78**, between the surface of the stable cartilage **78** and muscle tissue **79** adjacent thereto.

It is noteworthy that in many instances the needle **54** may be inserted into a joint from opposing directions. For example, the anchor member **50** was deposited in the position shown in FIGS. **13** and **14** by a needle that penetrated the muscle tissue **79**. The needle could have been inserted from the opposing side of the joint (and not through the muscle tissue **79**) to deposit the anchor member **50** in the position occupied by the retainer **68** in FIGS. **13** and **14**. Accordingly, the positions of the anchor member **50** and the retainer **68** would be reversed from those shown in FIGS. **13** and **14**, but the loose cartilage **76** would still be held against the secure cartilage **78**. One reason for inserting the needle from the opposing side of the joint, as just explained, would be to avoid damaging any nerves or blood vessels that are present in the region of the muscle tissue **79**.

To prevent prolonged irritation of the surrounding tissue by the presence of the anchor member **50** and retainer **68**, it is particularly desirable to form the anchor member and retainer of material that can be gradually absorbed by the body of the patients as healing occurs. Resilient, synthetic materials that are gradually absorbable by the body are known for use in sutures and are desirable as materials for the anchor member and retainers of the present invention. One such material is an absorbable polymer known as poly-diaxonone (PDS), which is available from Ethicon, Inc., of Summerville, N.J.

Referring now to FIGS. **15–17**, an anchor member **80** is particularly adapted for use in anchoring a suture **82** to bond **96** so that the suture **82** may be used to reattach tissue **98** to the bone. The anchor member **80** is generally bullet-shaped having a rounded convex base **84** with two attached legs **86** extending from the base. The outer ends **85** of the legs are tapered and terminate in a sharp outer edges **87**. The anchor member **80** is formed of resilient material, and whenever the anchor member is in its relaxed state (FIG. **15**), the legs **86** diverge outwardly so that the outer edges **87** of the legs are spaced apart a maximum distance D. One end of a suture **82** is embedded within, or otherwise attached to, the base **84** of the anchor member **80**. Suture **82** extends outwardly from the base **84** between the legs **86**.

Preferably, the outer surface of the anchor member **80** carries a plurality of barbs **88**. The barbs **88** point outwardly, and away from the rounded convex base **84**. As a result, the

exposed sharp point of each barb **88** is directed generally toward the direction in which the suture **82** extends away from the base **84** of the anchor member **80**.

As shown in FIG. **16**, the anchor member **80** is inserted within the tip **93** of a hollow needle **90** ahead of the tip **91** of a tube **92** that is used to expel the anchor member **80** from the needle. The suture **82** extends through the bore of the tube **92**.

The anchor member **80** and the bore of the needle **90** are sized so that the anchor member is in a deformed position whenever it is lodged within the tip **93** of the needle. In the deformed position, the legs **86** of the anchor member are pressed together with the outer edges **87** of the legs being spaced apart a minimum distance D corresponding to the needle bore diameter. This distance D is less than the maximum distance D between the outer edges **87** as measured when the anchor member is in the relaxed position (FIG. **15**).

As noted, the anchor member **80** is formed of resilient material. Consequently, whenever the anchor member **80** is expelled from the needle **90**, the intrinsic resilience of the anchor member urges it into the relaxed position. As will now be explained, the tendency of the anchor member **80** to move from the deformed into the relaxed position provides a simple mechanism for anchoring the anchor member **80** in bone so that, in conjunction with the attached suture; there is provided a means for reattaching tissue to the bone to promote healing.

More particularly, with reference to FIG. **17**, a hole **100** is drilled into the bone **96** in the region where the tissue **98** is to be reattached to the bone. The hole diameter is less than the maximum distance D between the outer edges **87** of the anchor member, but greater than or equal to the bore diameter of the needle **90**. With the anchor member **80** within the tip **93** of the needle **90**, the tissue **98** is pierced by the needle in a manner as described earlier. The tip **93** of the needle is forced through the tissue **98** and then aligned with the hole **100**. Next, the anchor member **80** is expelled from the needle into the hole **100** by sliding the tube **92** toward the tip **93** of the needle **90** as described earlier with respect to FIGS. **3–5**.

Once expelled from the needle **90** into the hole **100**, the resilience of the anchor member **80** urges the outer edges **87** of the legs **86** to bear upon the bone within the hole **100**. With the outer edges **87** of the legs bearing upon the bone, any tension applied to the suture **82** causes the sharp edges **87** to dig into the bone to secure the anchor member within the hole. The barbs **88** also dig into the bone to supplement the anchoring effect of the legs **86**.

Preferably, the anchor member **80** is sized so that when it is positioned within the hole **100**, the outer edges **87** of the legs **86** are beneath a relatively dense bone layer **97** that is located at the surface of the bone **96**, and is known as the cortical layer **97**. As a result, tension in the suture (in conjunction with the intrinsic resilient force of the anchor member **80** that forces the leg edges **87** apart) tends to lodge the edges **87** of the anchor member legs beneath the cortical layer **97**, rendering the anchor member substantially irremovable from the hole **100**.

As shown in FIG. **17**, a retainer **68**, as described earlier, may be employed with the suture **82** to secure the tissue **98** to the bone **96**.

FIG. **18** illustrates another technique for securing tissue **99** to the bone **96**, wherein two anchor members **80** are anchored in holes **101**, **103**, and the free ends of the sutures **82** are tied together over the tissue.

It is noted that it may not be necessary to first pierce the tissue **99** before depositing the anchor member **80** into the hole **101**, **103**. For instance, the anchor member **80** may be deposited within the hole **101**, **103** in the manner described above, and the free end of the suture **82** may be threaded through a conventional surgical needle that is used to pierce the tissue. The surgical needle is then removed and the free ends of the sutures **82** are secured as described above.

FIG. **19** depicts an alternative embodiment of an anchor member **110** suitable for anchoring in bone. The anchor member **110** is substantially similar to the anchor member **80** described earlier, except that it includes a continuous passage **112** formed therein to pass into one leg **114**, through the base **116**, and out the other leg **115**. The suture **118** is threaded through the hole passage **112** so that two suture segments **120** extend from the anchor member. This configuration of the anchor member **110** allows the user to select any type of suture for use with the anchor member **110**, depending upon the particular surgical needs. Further, having two suture segments **120** available for securing the tissue to the bone is often desirable. For example, whenever an odd number of anchor members **116** is used, the resulting even number of available suture segments **120** permits each segment of one anchor member to be tied to a corresponding segment of an adjacent anchor member, without the need for tying more than two suture segments together.

FIGS. **20** and **21** illustrate a side sectional view and top view, respectively, of another alternative embodiment of an anchor member **130** formed in accordance with this invention. This embodiment is a generally cup-shaped piece of resilient material, such as plastic, having a base **132** with four legs **134** extending upwardly therefrom. The sharp outer edge **136** of each leg is spaced apart from an opposing edge **136** by a maximum distance D whenever the anchor member is in the relaxed position as shown in FIG. **20**. As noted earlier, distance D is greater than the diameter of the hole into which the anchor member **130** is deposited. Preferably, two holes **138** are formed in the base **132** of the anchor member **130**. A suture **140** is threaded through the holes **138**.

The anchor member **130** is deposited within a hole in a bone in a manner similar to that explained with respect to the apparatus of FIG. **16**. Specifically, the anchor member **130** is positioned within the tip of a hollow needle (not shown) where it assumes a deformed position. In the deformed position, the outer edge **136** of each leg is held near the outer edge **136** of the opposing leg a distance D that is less than the "relaxed" distance D and corresponds to the diameter of the needle bore in which the anchor member is lodged. When the anchor member **130** is expelled from the needle and deposited within the hole in the bone, the intrinsic resilience of the anchor member **130** forces the outer edges **136** against the bone, thereby anchoring the anchor member within the hole. The suture **140** is thereafter available to secure tissue against the bone as discussed above.

The anchor members **80**, **110**, **130** just described may be formed of material that is absorbable by the body. Alternatively, the anchor members may be formed of non-absorbable material (e.g., stainless steel of suitable resilience) that remains in the bone indefinitely.

The terms and expressions that have been employed in the foregoing specification are used herein as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding equivalents of the features shown and described or portions thereof, it being recognized that the scope of the invention is defined and limited only by the claims that follow.

I claim:

1. A method for anchoring in bone a member and attached suture, comprising the steps of:

forming a hole in the bone;

attaching a suture to a member;

lodging the member within the hole by pressing the member with attached suture into the hole; and

attaching tissue to the suture so that the tissue is secured against the bone.

2. A method for anchoring in bone a member and attached suture, comprising the steps of:

forming a hole in the bone;

attaching a suture to a member;

lodging the member within the hole by pressing the member with attached suture into the hole; and

deforming the member in a manner such that the member resiles against the portion of the bone that defines the hole.

3. A method for anchoring in bone a member and attached suture, comprising the steps of:

forming a hole in the bone;

attaching a suture to a member by threading the suture through a passage in the member so that neither end of the suture is fastened to the member; and

lodging the member within the hole by pressing the member with attached suture into the hole.

4. The method of claim **1** wherein the tissue is a non-bony tissue.

5. The method of claim **4** wherein the tissue is a member of the group consisting of cartilage, tendon, or ligament.

6. A method of anchoring in bone a member and attached suture, comprising the steps of:

providing a deformable member having a width dimension "D";

attaching a suture to the member;

forming a hole in a bone in a manner such that the hole has a diameter that is not greater than the width dimension "D"; and

inserting the member into the hole with the member oriented such that the member lodges within the hole in the absence of any manipulation of the member other than inserting the member into the hole.

7. The method of claim **6** wherein the attaching step includes threading the suture through the member so that the suture defines two contiguous segments extending from the member.

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

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CERTIFICATE OF COMPLIANCE

Defendant-Appellants' Brief is submitted in accordance with Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure. The Brief contains 9,736 words, as determined by Microsoft Word.

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